Australian Network of Environmental Defender's Offices Inc

Submission regarding the Agriculture and Veterinary Chemicals Legislation Amendment (Removing re-approval and re-registration) Bill 2013

7 March 2014

The Australian Network of Environmental Defender's Offices (ANEDO) consists of nine independently constituted and managed community environmental law centres located in each State and Territory of Australia.

Each EDO is dedicated to protecting the environment in the public interest. EDOs provide legal representation and advice, take an active role in environmental law reform and policy formulation, and offer a significant education program designed to facilitate public participation in environmental decision making.

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Executive Summary

ANEDO welcomes the opportunity to comment on the *Agriculture and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013* (Cmth) (**Agvet Bill**). We note that this Bill is intended to amend the *Agricultural and Veterinary Chemicals Code Act 1994* (Cmth) (**Agvet Act**).

ANEDO is concerned by the proposal to remove key components of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Cmth) (**2013 Amendments**), in particular provisions concerning:

- removal of re-approval of chemical constituents;
- removal of re-registration of chemical products;
- amendments to variation of approval or registration dates based on the decisions of foreign regulators; and
- amendments to reporting arrangements for import, export and manufacture of technical grade active constituents.

Insufficient time has lapsed since the 2013 Amendments to determine whether the provisions contained therein impose an unreasonable burden on the agricultural sector.

Given broad community concern regarding the proper regulation of chemical constituents and chemical products, we would advocate reviewing the 2013 Amendments in five to ten years' time. The purpose of such a review would be to ascertain the environmental and safety benefits on the one hand, and costs to the industry on the other, of the current re-approval, re-registration, renewal and reporting scheme.

Subsequent amendments (if any) would need to be based on best available scientific and socio-economic analysis. They would also have to reflect s. 1A of the Agvet Act, which requires (*inter alia*) the Agvet Code to be implemented in a manner that:

> *a) recognises the health and safety of human beings, animals and the environment is the first priority of the system for regulating chemical products and their constituents, in part to ensure that the use of chemical products at the present time will not impair the prospects of future generations; and*
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> *b) reflects established best practice principles for the assessment and management of risk, based on science; and*
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> …
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> *e) promotes community confidence in the regulation of chemical products and their constituents, is open and accountable, and gives the opportunity for public participation; and…*

This recommendation is further based on the nature and scope of chemical regulation in comparable jurisdictions. For example, chemical legislation in Europe[1] and the United States[2]

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[1] *European Union Regulations 1107/2009,* Articles 15 – 17.

[2] *Federal Insecticide, Fungicide, and Rodenticide Act* (as amended by the *Pesticides Registration Improvement Act 2003* and the *Pesticide Registration Improvement Act 2003*). Re-registration provisions were introduced in 1988 and sought to provide a comprehensive review of both human health and ecological effects of ingredients in pesticides that were registered prior to November 1, 1984. Broadly speaking, the re-registration programme utilised supporting scientific studies, human health and ecological risk assessments, and developed risk mitigation measures in accordance with current scientific safety standards and input from public consultation. Registration review will replace the EPA pesticide re-registration and tolerance reassessment programs once these programs are

provides for regular review of chemical registration.[3] Australia should seek to ensure that its re-approval and re-registration framework is at the very least comparable to the frameworks found in these two jurisdictions. This would require strengthening, rather than weakening, the Agvet Act.

Recommendations

1. Maintain and improve the current re-approval and re-registration scheme. Improvement would take the form of:

    a. additional criteria regarding environmental impacts. This would require the amendment of s. 14 of the Agvet Act.

    b. introducing more frequent re-approval and re-registration (between every five and ten years, based on risk).

2. Limit simpler variations to approvals and registrations where the most up-to-date, peer-reviewed evidence indicates that the variation will not have an adverse impact on human health or the environment. To clarify, in many instances the variation of formulations does not constitute a 'simple variation.'

3. Maintain the current provisions regarding the decisions of foreign regulators.

4. Maintain the current obligation to report import, export and manufacture of technical grade chemical constituents.

5. Where the Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is asked to provide information to a company responsible for a chemical product, payments for that information should be sufficiently high to provide the company with an incentive to maintain proper administrative practices.

6. Conduct a review of the 2013 Amendments in five to ten years' time. The review should ascertain, on the basis of best available science and socio-economic analysis, the benefits to human health and the environment on the one hand, and costs to the agricultural sector on the other, of the Amendments.

Removal of re-approval and re-registration: questions (a) – (d)

ANEDO does not support the removal of re-approval and re-registration provisions, which were introduced following the 2013 Amendments with a view reducing risks to human health and the environment without unduly burdening the agricultural sector. As noted in the explanatory memoranda to the 2013 Amendments,

> *Schedule 2 amends the Agvet Code to ensure the ongoing safety of agvet chemicals and improve the effectiveness and efficiency of agvet chemical reconsideration arrangements. This is achieved by*

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completed. The Registration review differs from reregistration as it operates continuously and covers all pesticides. Each registered pesticide will be reviewed every 15 years to ascertain whether it still satisfies the FIFRA standard for registration. See: http://www.epa.gov/oppsrrd1/registration_review/highlights.htm

[3] Department of Agriculture, Fisheries and Forestry, *Better Regulation of Agriculture and Veterinary Chemical Products: Regulation Impact Statement*, November 2001, p. 11.

> *implementing a mandatory scheme for the re-approval of active constituents and re-registration of chemical products to periodically review (every 7-15 years) active constituents and products to ensure that they do not pose unacceptable risks to human or environmental health and safety . The scheme is designed to minimise impacts on affected businesses.*[4]

ANEDO understands that all regulation must be based on some degree of cost-benefit analysis. However, we submit that there is little logic in removing these safeguards before adequate evidence can be gathered to determine their benefit to the community and the environment on the one hand, and cost to the industry on the other.

Further to this point, ANEDO could find no peer-reviewed evidence to suggest that the 2013 Amendments had imposed an unreasonable burden on the agricultural sector, taking into account the potential for human harm posed by agvet chemicals. Indeed, as re-approval and re-registration need only take place every seven to 15 years,[5] many chemical constituents and chemical products are yet to be subject to the new provisions. It is therefore impossible to argue that re-approval and re-registration is unduly burdensome.

We further note that a significant number of 'grandfathered chemicals' were introduced with the National Registration Scheme in 1995. Many of these chemicals have not been properly assessed against the latest scientific information, yet remain in use in Australia. As noted by the Productivity Commission:

> *Over 5000 of the 6500 agvet chemical products currently available in Australia were registered under the previous arrangements, often involving less rigorous assessments, some of which dated back to the 1950s.*[6]

While Australian National Audit Office (**ANAO**) audit of the APVMA found that the APVMA had 'reasonable arrangements for identifying and prioritising existing [grandfathered] chemicals requiring review', the audit found that progress was slow. Specifically, '…even for the relatively small subset of existing chemicals identified and prioritised for review, ANAO noted the slow rate of progress in commencing and completing reviews.' The Productivity Commission further noted that 'ANAO found that the average time to review an existing chemical was nearly three years, and this was set to increase because many of the reviews in progress have already taken more than five years.'[7]

Given the institutional limitations regarding the review of grandfathered agvet chemicals, it seems prudent to maintain a systematic re-registration and re-approval scheme. A systematic scheme will ensure review of all agvet chemicals, while ad-hoc assessment is likely to result in (potentially dangerous) omissions.

More generally, failure to regularly review chemical constituents and products via the re-approval and re-registration scheme may mean that the APVMA's management practices do not reflect the latest scientific information.

The importance of embedding a regular review mechanism that incorporates best-available knowledge cannot be overstated. Numerous chemicals have been banned as new evidence emerged regarding their impacts on human health and the environment. For example, the

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[4] Available at: http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fems%2Fr4941_ems_d22b91df-28ad-4f9b-a769-5f3cd16cc947%22#_Toc340507004.

[5] Agvet Act, ss. 29J (2), 29K (2).

[6] Productivity Commission, *Chemicals and Plastics Regulation, Chapter 8: Registration of agricultural and veterinary chemical products*, 2008, p. 209.

[7] Ibid.

Stockholm Convention on Persistent Organic Pollutants (**Convention**) requires signatories to prohibit or phase out a prescribed list of persistent organic pollutants (**POPs**).

Support for the Convention was based on mounting scientific evidence regarding the deleterious impacts of POPs. According to the United States Environmental Protection Agency, '[a] major impetus for the Stockholm Convention was the finding of POPs contamination in relatively pristine Arctic regions - thousands of miles from any known source."[8] This discovery prompted scientists and regulators to reconsider their understanding of the movement of POPs, which in turn resulted in a coordinated, international response to the management of these pollutants.

Simpler variations to approvals and registrations: questions (j) – (k)

ANEDO would only support the simplification of variations to approvals and registrations where it was known that the variation could not have an adverse impact on human health or the environment.

With this in mind, we submit that 'simple formulation changes' do not necessarily constitute a 'simple variation.' Formulation changes can alter the toxicity of both the active constituent and product. As noted by the Swedish Chemicals Agency,

> *Empirical evidence on the toxicity and ecotoxicity of such chemical cocktails shows one common pattern, independent of the specific chemical composition of a particular mixture, the exposed organism or biological endpoint under observation: the joint toxicity of a chemical mixture is always higher than the individual toxic effect of even the most potent compound present. In particular, even low, individually non-toxic concentrations might result in significant toxicity, if they co-occur as a chemical mixture.*[9]

Reporting import, export and manufacture of technical grade active constituents: question (l)

ANEDO does not support removing the current obligation[10] to report the import, export and manufacture of technical grade active constituents.

A technical grade active constituent is a substance that is 'primarily responsible for the biological or other effect identifying the product as an agricultural chemical product or veterinary chemical product."[11] If the technical grade active constituent is not made into product, it still poses environmental and health risk. As such, the storage and disposal of this product should be of equivalent concern to APVMA with regards to environmental and human health, as chemical products.

The APVMA should require information about the quantities of technical grade active constituent in order to effectively track and manage these chemicals and this information should be reconcilable with information on quantities of chemical product manufactured or

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[8] http://www.epa.gov/international/toxics/pop.html

[9] Swedish Chemicals Agency, *Hazard and Risk Assessment of Chemical Mixtures under REACH: State of the Art, Gaps and Options for Improvement*, 2010, p. 8.

[10] *Agriculture and Veterinary Chemicals (Administration) Act 1992*, s. 69E (1). Chemical constituents below a quantity prescribed in the regulations are not subject to this obligation: 69E (2).

[11] NRA Gazette 9 3 September 2002 - Page 52. Accessed at http://www.apvma.gov.au/publications/gazette/2002/09/gazette0209p52.php accessed on 17 February 2014

alternatively with waste tracking records, to ensure all technical grade active constituent is either used or properly disposed.

Decisions of foreign regulators (not addressed by consultation paper)

The Agvet Act currently provides for the Regulator to vary the duration of an approval or registration where two or more prescribed foreign regulators have decided, within a seven year period, to prohibit the use of the same active constituent or chemical product due to impacts on human health or the environment.[12]

While this provision is not discussed in the consultation paper, scrutiny of the Agvet Bill reveals that that the proposed amendments will remove this requirement.

ANEDO supports maintaining this provision as it assists to capture potentially hazardous chemical constituents and products between formal re-approval and re-registration periods.

Providing companies responsible for a product with access to information about the product for a fee: question (o)

The consultation paper notes that 'the APVMA is often asked to provide information to the company that is responsible for a chemical product about products it has registered (including about the formulation and details of manufacturing).'

ANEDO is concerned that any company involved in the Agvet chemical supply chain would be unable to effectively maintain adequate records, including records which they are required to provide to the APVMA under existing legislation. It is arguable that such companies may be unfit to manage the production, importation, exportation, sale and use of chemicals in an appropriate manner and keep the APVMA informed of changes to those chemicals.

The APVMA should be treating such requests with a similar degree of concern, particularly as certain measures described in the Agvet Bill will enable greater industry self-regulation.

Accordingly, payments for information should be sufficiently high to provide companies with an incentive to maintain proper administrative practices.

[12] Agvet Act, s. 47A.